



General

Guideline Title

Antiemetics: American Society of Clinical Oncology clinical practice guideline update.

Bibliographic Source(s)

Basch E, Prestrud AA, Hesketh PJ, Kris MG, Feyer PC, Somerfield MR, Chesney M, Clark-Snow RA, Flaherty AM, Freundlich B, Morrow G, Rao KV, Schwartz RN, Lyman GH. Antiemetics: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. 2011 Nov 1;29(31):4189-98. [56 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Kris MG, Hesketh PJ, Somerfield MR, Feyer P, Clark-Snow R, Koeller JM, Morrow GR, Chinnery LW, Chesney MJ, Gralla RJ, Grunberg SM. American Society of Clinical Oncology guideline for antiemetics in oncology: update 2006. J Clin Oncol 2006 Jun 20;24(18):1-16. [110 references]

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

•	May 10, 2016 - Olanzapine : The U.S. Food and Drug Administration (FDA) is warning that the antipsychotic
	medicine olanzapine can cause a rare but serious skin reaction that can progress to affect other parts of the body. FDA is adding a new
	warning to the drug labels for all olanzapine-containing products that describes this severe condition known as Drug Reaction with
	Eosinophilia and Systemic Symptoms (DRESS).

Recommendations

Major Recommendations

Chemotherapy-Induced Nausea and Vomiting

Highly and moderately emetogenic antineoplastic agents have the potential to induce both acute (≤24 hours) and delayed (>24 hours) nausea and vomiting after chemotherapy. The guideline recommendations include prophylaxis for both types of nausea and vomiting where appropriate.

This guideline update includes the most recent recommendations (see Table 1 in the original guideline document) developed by the Update Committee. A table with intravenous agents organized by emetic risk is included below. The intravenous risk stratification schema was originally published in 1997 and was updated at the Multinational Association of Supporting Care in Cancer (MASCC)/European Society for Medical Oncology 2009 consensus conference. The modified stratification from MASCC was adopted by ASCO for this guideline update. Dosing schedules are also detailed (see Table 3 in the original guideline document).

Table. Emetic Risk of Intravenous Antineoplastic Agents

Emetic Risk	Agent
High	Carmustine Cisplatin Cyclophosphamide ≥1,500 mg/m² Dacarbazine Dactinomycin Mechlorethamine Streptozotocin
Moderate	Azacitidine Alemtuzumab Bendamustine Carboplatin Clofarabine Cyclophosphamide <1,500 mg/m² Cytarabine >1,000 mg/m² Daunorubicin* Doxorubicin* Epirubicin* Idarubicin* Ifosfamide Irinotecan Oxaliplatin
Low	Fluorouracil Bortezomib Cabazitaxel Caturnaxomab Cytarabine ≤1,000 mg/m² Docetaxel Doxorubicin HCL liposome injection Etoposide Gemeitabine Ixabepilone Methotrexate Mitomycin Mitoxantrone Paclitaxel Panitumumab Pemetrexed Temsirolimus Topotecan Trastuzumab

Minimal Emetic Risk	2-Chlorodeoxyadenosine Bevacizumab
	Bleomycin
	Busulfan
	Cetuximab
	Fludarabine
	Pralatrexate
	Rituximab
	Vinblastine
	Vincristine
	Vinorelbine

Data adapted from Gralla RJ, Roila F, Tonato M, et al: MASCC/ESMO antiemetic guideline 2010. http://www.mascc.org/mc/page.do?sitePageId88041

Note: This list of agents is not exhaustive.

Clinical Question 1

What is the optimal treatment to prevent nausea and vomiting from highly emetogenic antineoplastic agents?

Recommendation 1. The three-drug combination of a neurokinin 1 (NK₁) receptor antagonist (days 1 through 3 for aprepitant; day 1 only for fosaprepitant), a 5-hydroxytryptamine-3 (5-HT₃) receptor antagonist (day 1 only), and dexamethasone (days 1 through 3 or 1 to 4) is recommended for patients receiving highly emetogenic chemotherapy. This recommendation remains unchanged since the 2006 update but has been reworded for clarification. The Update Committee also recommended reclassification of the combined anthracycline and cyclophosphamide (AC) regimen as highly emetogenic.

Clinical Question 2

What is the optimal treatment to prevent nausea and vomiting from moderately emetogenic antineoplastic agents?

Recommendation 2. The two-drug combination of palonosetron (day 1 only) and dexamethasone (days 1 through 3) is recommended for patients receiving moderately emetogenic chemotherapy. If palonosetron is not available, clinicians may substitute a first generation 5-HT₃ receptor antagonist, preferably granisetron or ondansetron.

Limited evidence also supports adding aprepitant to the combination. Should clinicians opt to add aprepitant for patients receiving moderate-risk chemotherapy, any one of the 5-HT $_3$ receptor antagonists is appropriate.

Clinical Question 3

What is the optimal treatment to prevent nausea and vomiting from low emetogenic antineoplastic agents?

Recommendation 3. A single 8-mg dose of dexamethasone before chemotherapy is suggested. No change from 2006.

Clinical Question 4

What is the optimal treatment to prevent nausea and vomiting from minimally emetogenic antineoplastic agents?

Recommendation 4. No antiemetic should be administered routinely before or after chemotherapy. No change from the original guideline.

Clinical Question 5

What is the optimal treatment to prevent nausea and vomiting from combination chemotherapy?

Recommendation 5. Patients should be administered antiemetics appropriate for the component chemotherapeutic (antineoplastic) agent of greatest emetic risk. No change from the original guideline. Anthracycline-cyclophosphamide combinations are now classified as highly emetogenic.

Clinical Question 6

^{*}These anthracyclines, when combined with cyclophosphamide, are now designated as high emetic risk.

What is the role of adjunctive drugs for nausea and vomiting induced by cancer treatments?

Recommendation 6. Lorazepam and diphenhydramine are useful adjuncts to antiemetic drugs but are not recommended as single agent antiemetics. No change from 2006.

Clinical Question 7

What is the role of complementary and alternative medicine therapies to prevent or control nausea and vomiting induced by chemotherapy?

Recommendation 7. No published randomized controlled trial data meeting the inclusion criteria are currently available to support a recommendation about such therapies.

Special Populations

Clinical Question 8

What is the optimal treatment to prevent nausea and vomiting associated with cancer therapy for pediatric patients?

Recommendation 8. The combination of a 5-HT₃ receptor antagonist plus a corticosteroid is suggested before chemotherapy in children receiving chemotherapy of high or moderate emetic risk. Because of the variation of pharmacokinetic parameters in children, weight-based doses of 5-HT₃ receptor antagonists higher than those used in adults may be required for antiemetic protection. No change from 2006.

Clinical Question 9

What is the optimal treatment to prevent nausea and vomiting in patients who are undergoing high-dose chemotherapy with stem-cell or bone marrow transplantation?

Recommendation 9. A 5-HT₃ receptor antagonist combined with dexamethasone is recommended. Aprepitant should be considered, although evidence to support its use is limited.

Clinical Question 10

What is the optimal treatment to prevent nausea and vomiting for patients receiving multiday chemotherapy?

Recommendation 10. It is suggested that antiemetics appropriate for the emetogenic risk class of the chemotherapy be administered for each day of the chemotherapy and for 2 days after, if appropriate. No change from the original guideline. The Update Committee suggests, on the basis of limited data, that patients receiving 5-day cisplatin regimens be treated with a 5-HT₃ receptor antagonist in combination with dexamethasone and aprepitant.

Clinical Question 11

What is the optimal antiemetic regimen for patients who experience nausea and vomiting secondary to cancer therapy despite optimal prophylaxis?

Recommendation 11. Language from the 2006 guideline was reformatted for clarity. Clinicians should (1) re-evaluate emetic risk, disease status, concurrent illnesses, and medications; (2) ascertain that the best regimen is being administered for the emetic risk; (3) consider adding lorazepam or alprazolam to the regimen; and (4) consider adding olanzapine to the regimen or substituting high-dose intravenous metoclopramide for the 5-HT₃ receptor antagonist or adding a dopamine antagonist to the regimen.

Clinical Question 12

What treatment options are available for patients who experience anticipatory nausea and vomiting?

Recommendation 12. Use of the most active antiemetic regimens appropriate for the chemotherapy being administered to prevent acute or delayed emesis is suggested. Such regimens should be used with initial chemotherapy, rather than assessing the patient's emetic response with less effective treatment. If anticipatory emesis occurs, behavioral therapy with systematic desensitization is effective and suggested. No change from the original guideline.

Radiation-Induced Nausea and Vomiting

This guideline update includes an updated risk stratification table according to site of radiation treatment. The Multinational Association of Supportive Care in Cancer (MASCC) updated the radiation therapy emetic risk table at the MASCC/European Society for Medical Oncology

2009 consensus conference (see Table, below); this was adopted by the American Society for Clinical Oncology (ASCO) for this guideline update. Dosing schedules, according to risk level, are detailed in Table 2 in the original guideline document.

Table. Emetic Risk by Site of Radiation Therapy

Emetic Risk	Site of Radiation Therapy
High	Total-body irradiation Total nodal irradiation
Moderate	Upper abdomen Upper body irradiation Half-body irradiation
Low	Cranium Craniospinal Head and neck Lower thorax region Pelvis
Minimal	Extremities Breast

Data adapted from	n Gralla RJ, Roila F, Ton	ato M, et al: MASCC/ESMO	antiemetic guideline 2010	. http://www.mascc.org/n	rc/page.do?
sitePageId88041					

Clinical Question 13

What is the optimal prophylaxis for nausea and vomiting caused by high emetic risk radiation therapy?

Recommendation 13. On the basis of extrapolation from indirect evidence, the Update Committee recommends that all patients receive a 5-HT₃ receptor antagonist before each fraction and for at least 24 hours after completion of radiotherapy. Patients should also receive a 5-day course of dexamethasone during fractions 1 to 5.

Clinical Question 14

What is the optimal prophylaxis for nausea and vomiting caused by moderate emetic risk radiation therapy?

Recommendation 14. The Update Committee recommends that patients receive a 5-HT3 receptor antagonist before each fraction for the entire course of radiotherapy. Patients may be offered a short course of dexamethasone during fractions 1 to 5.

Clinical Question 15

What is the optimal treatment to manage nausea and vomiting associated with low emetic risk radiation therapy?

Recommendation 15. The Update Committee recommends a 5-HT₃ receptor antagonist alone as either prophylaxis or rescue. For patients who experience radiation-induced nausea and vomiting (RINV) while receiving rescue therapy only, prophylactic treatment should continue until radiotherapy is complete.

Clinical Question 16

What is the optimal treatment to manage nausea and vomiting associated with minimal emetic risk radiation therapy?

Recommendation 16. Patients should receive rescue therapy with either a dopamine receptor antagonist or a 5-HT₃ receptor antagonist. Prophylactic antiemetics should continue throughout radiation treatment if a patient experiences RINV while receiving rescue therapy.

Clinical Question 17

What is the optimal treatment to manage nausea and vomiting during concurrent radiation and chemotherapy?

Recommendation 17. Patients should receive antiemetic prophylaxis according to the emetogenicity of chemotherapy, unless the emetic risk with



Adult and pediatric patients with cancer receiving chemotherapy or radiation therapy

Interventions and Practices Considered

- 1. Assessment of patient's risk for emesis
- 2. Antiemetic pharmacotherapy
 - Neurokinin 1 (NK₁) receptor antagonists
 - 5-hydroxytryptamine-3 (5-HT₃) receptor antagonists
 - Corticosteroids
 - Dopamine receptor antagonists
- 3. Adjunctive drugs
 - · Lorazepam, alprazolam, diphenhydramine

Major Outcomes Considered

- Complete response
- Emetic episodes
- Nausea control
- Use of rescue antiemetics

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Strategy

The initial search for this systematic review identified relevant articles from an Agency for Healthcare Research and Quality—funded Evidence-Based Practice Center report completed at Oregon Health and Science University (OHSU). The dates of the OHSU literature search of MEDLINE were 1966 through October 2008. That evidence review was limited to trials including the newer antiemetics: aprepitant (neurokinin 1 [NK₁] receptor antagonist) and 5-hydroxytryptamine-3 (5-HT₃) receptor antagonists. Initially, two literature searches of MEDLINE were completed by American Society of Clinical Oncology (ASCO) staff. The first included all relevant search terms (see the Data Supplement [see the "Availability of Companion Documents" field]), overlapping minimally with the OHSU search, from September 2008 through December 2009. A second search, excluding the OHSU intervention search terms, overlapped briefly with the search for the 2006 ASCO update, ranging from February 2004 to February 2010. This second search was designed to identify new adjunctive therapy. The Cochrane Collaboration Library electronic database was also searched, using the terms emesis, vomiting, and nausea. Data presented at the ASCO and the Multinational Association of Supportive Care in Cancer (MASCC) annual meetings available since the 2006 update were also searched systematically using the terms vomiting, emesis, and nausea, but only presentations or posters were included. Data presented only in abstract form were excluded. Yield from hand searches of bibliographies from relevant articles and materials provided by Update Committee members was also assessed for inclusion. Another search of MEDLINE was completed, including all intervention terms, after preparation of the preliminary draft to determine if any new trials had been published. Meeting materials were not searched again.

Inclusion and Exclusion Criteria

Trial reports of randomized studies or other systematic reviews from scholarly articles or meetings eligible for inclusion met the following criteria: (1) intervention was for the treatment of nausea or vomiting secondary to cancer therapy, (2) nausea and/or vomiting outcomes were reported, (3) patients were observed for a minimum of 5 days (120 hours) after initial chemotherapy administration, and (4) each trial arm included a minimum of 25 randomly assigned patients.

Number of Source Documents

Thirty-seven trials met pre-specified inclusion and exclusion criteria for this systematic review. Two systematic reviews from the Cochrane Collaboration were identified; one surveyed the pediatric literature. The other compared the relative efficacy of the 5-hydroxytryptamine-3 (5-HT₃) receptor antagonists.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction

Eligible reports were identified in a first round of review by an American Society of Clinical Oncology (ASCO) staff member; these were later discussed with the Co-Chairs to reach a final decision. Full text copies were obtained for assessment of inclusion/exclusion criteria. Articles that provisionally met inclusion criteria underwent data extraction by ASCO staff for patient characteristics, study design and quality, interventions, outcomes, and adverse events. Evidence summary tables (Data Supplement; see the "Availability of Companion Documents" field) were reviewed for accuracy and completeness by an ASCO staff member who was not involved in their original preparation.

Study Quality

Trial characteristics extracted to rate quality included study design, definition of terms, and outcomes.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Panel Composition

An Update Committee was formed to review data published since 2006 and develop updated recommendations.

Consensus Development Based on Evidence

The 2011 Update Committee met once at the American Society of Clinical Oncology (ASCO) Headquarters Office and once via teleconference to consider available evidence and develop recommendations. Additional work on the guideline was completed electronically. Members of the steering committee and ASCO staff prepared a draft guideline document that was disseminated for review by the entire Update Committee.

Update Methodology

This update reviewed 5-hydroxytryptamine-3 (5-HT3) receptor antagonist equivalency, considering use of these agents either with or without a neurokinin $1 (NK_1)$ receptor antagonist. Other key questions included the use of NK_1 receptor antagonists in the moderately emetogenic and high-dose chemotherapy setting, the use of alternative drug formulations, and antiemetic therapy for children; the complete list of questions included in this guideline update is provided in the original guideline document.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

As per standard American Society of Clinical Oncology (ASCO) practice, the guideline was submitted to *Journal of Clinical Oncology* for peer review. Feedback from external reviewers with expertise in antiemetics was also solicited. The Update Committee, the ASCO Clinical Practice Guideline Committee, and the ASCO Board of Directors reviewed and approved the final document.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on 37 randomized controlled trials and two systematic reviews. Refer to the "Literature Update and Analysis" sections of the original guideline document for specific evidence for each recommendation.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of antiemetics based on patient's emetic risk category

Potential Harms

Adverse events associated with use of antiemetics include constipation, diarrhea, and headache.

Qualifying Statements

Qualifying Statements

Guideline Policy

This practice guideline is not intended to substitute for the independent professional judgment of the treating physician. Practice guidelines do not account for individual variation among patients and may not reflect the most recent evidence. This guideline does not recommend any particular product or course of medical treatment. Use of the practice guideline is voluntary.

Limitations of the Literature

One limitation of the trials was that a number of studies included patients who received either moderately or highly emetogenic chemotherapy without reporting subset analyses for patient groups according to emetic risk. Findings from such combined trials are challenging to interpret in the context of an evidence-based recommendation for a specific risk class.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Basch E, Prestrud AA, Hesketh PJ, Kris MG, Feyer PC, Somerfield MR, Chesney M, Clark-Snow RA, Flaherty AM, Freundlich B, Morrow G, Rao KV, Schwartz RN, Lyman GH. Antiemetics: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. 2011 Nov 1;29(31):4189-98. [56 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1999 Sep (revised 2011 Nov 1)

Guideline Developer(s)

American Society of Clinical Oncology - Medical Specialty Society

Source(s) of Funding

American Society of Clinical Oncology

Guideline Committee

2011 Update Committee

Composition of Group That Authored the Guideline

Committee Members: Ethan Basch, MD (Co-Chair), Memorial Sloan-Kettering Cancer Center; Gary H. Lyman, MD, (Co-Chair), Duke University; Paul J. Hesketh, MD, Steering Committee, Lahey Clinic Medical Center; Mark G. Kris, MD, Steering Committee, Memorial Sloan-Kettering Cancer Center; Maurice Chesney, Patient Representative; Rebecca Anne Clark-Snow, RN, Lawrence Memorial Hospital Oncology Center; Petra C. Feyer, MD, Vivantes Clinic of Radiooncology and Nuclear Medicine; Anne Marie Flaherty, RN, Memorial-Sloan Kettering Cancer Center; Barbara Freundlich, BA, Patient Representative; Gary Morrow, PhD, University of Rochester Cancer Center; Kamakshi V. Rao, PharmD, University of North Carolina Hospital; Rowena N. Schwartz, PharmD, BCOP, CPP, The Johns Hopkins Hospital

Financial Disclosures/Conflicts of Interest

Although all authors completed the disclosure declaration, the following author(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

Employment or Leadership Position: None Consultant or Advisory Role: Paul J. Hesketh, GlaxoSmithKline (C), Helsinn (C), Merck (C); Mark G. Kris, sanofi-aventis (C), GlaxoSmithKline (C); Petra C. Feyer, GlaxoSmithKline (C), Merck (C) Stock Ownership: None Honoraria: Rebecca

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Guideline Status

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Cuidalina Availability
Guideline Availability
Electronic copies: Available from the American Society of Clinical Oncology (ASCO) Web site
Print copies: Available from American Society of Clinical Oncology, Cancer Policy and Clinical Affairs, 2318 Mill Rd, Suite 800, Alexandria, VA 22314; E-mail: guidelines@asco.org
Availability of Companion Documents
The following are available:
 Antiemetics: American Society of Clinical Oncology clinical practice guideline update. Executive summary. J Oncol Pract 2011 Nov; 7(6). Electronic copies: Available from the American Society of Clinical Oncology (ASCO) Web site Antiemetics: American Society of Clinical Oncology clinical practice guideline update. Data supplements. Alexandria (VA): American Society of Clinical Oncology; 2011. 27 p. Electronic copies: Available in Portable Document Format (PDF) from the ASCO Web site Guideline update on antiemetics. American Society of Clinical Oncology guideline. Slide set. Alexandria (VA): American Society of Clinical Oncology; 2011. 38 p. Electronic copies: Available in Portable Document Format (PDF) and PowerPoint from the ASCO Web site. Drug, dose, schedule recommendations for antiemetic regimens. Alexandria (VA): American Society of Clinical Oncology; 2011. 3 p. Electronic copies: Available in Portable Document Format (PDF) from the ASCO Web site Antimetics 2001 guideline update. Podcast. Alexandria (VA): American Society of Clinical Oncology; 2011. Available from the ASCO Web site
Patient Resources
The following is available:

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

. A podcast is also available from the Cancer. Net Web site

• What to know: ASCO's guideline on preventing vomiting caused by cancer treatment. 2011. Electronic copies available from the

NGC Status

Cancer.Net Web site

This summary was completed by ECRI on January 3, 2000. It was verified by the guideline developer on January 18, 2000. This NGC summary was updated by ECRI Institute on April 1, 2009 following the FDA advisory on Reglan (metoclopramide). This summary was updated by ECRI Institute on May 1, 2009 following the U.S. Food and Drug Administration advisory on antiepileptic drugs. This summary was updated by ECRI Institute on January 12, 2011 following the U.S. Food and Drug Administration advisory on Anzemet (dolasetron mesylate). This NGC summary was updated by ECRI Institute on December 8, 2011. This summary was updated by ECRI Institute on September 10, 2012 following the U.S. Food and Drug Administration advisory on Ondansetron (Zofran). This summary was updated by ECRI Institute on December 12, 2012 following the U.S. Food and Drug Administration advisory on Ondansetron (Zofran). This summary was updated by ECRI Institute on May 24, 2016 following the U.S. Food and Drug Administration advisory on Ondansetron (Zofran). This summary was updated by ECRI Institute on May 24, 2016 following the U.S. Food and Drug Administration advisory on Olanzapine.

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